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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,471	07/05/2001	Zeren Gao	00-46	3433

7590 07/29/2003

Phillip B.C. Jones, J.D., Ph.D.
ZymoGenetics, Inc.
1201 Eastlake Avenue East
Seattle, WA 98102

EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/29/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/899,471

Applicant(s)

GAO, ZEREN

Examiner

Dong Jiang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 14, 15 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-15 and 17-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED OFFICE ACTION

Applicant's amendment in paper No. 12, filed on 29 April 2003 is acknowledged and entered. Following the amendment, claim 16 is canceled, and claim 8 is amended.

Currently, claims 1-15 and 17-20 are pending, and claims 8-13 are under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claim 16 are moot as the applicant has canceled the claim.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-13 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by a credible, substantial, and specific, or a well-established utility, for the reasons set forth in the last Office Action, paper No. 9, mailed on 26 November 2002, at pages 2-4.

Applicants argument, filed on 29 April 2003 (paper No. 12) has been fully considered, but is not deemed persuasive for reasons below.

At pages 4-5 of the response, citing the Utility Examination Guidelines and MPEP that a patent examiner must accept a utility asserted by an applicant unless the examiner has sound scientific reasoning to rebut the assertion, and that the Office must ... provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the prima facie showing ..., the applicant argues that the Examiner has provided no evidence or scientific basis to refute the assertion of utility for the polypeptides of the present invention. Applicants further argue that one of skill in the art would appreciate that zcytor14 is a member of the sufficiently conserved IL-17R related family of proteins, and would reasonably *impute* the same specific, substantial, and credible utility to zcytor14. This argument is not persuasive because the issue is not that the Examiner does not accept the utility for the polypeptides of the present invention, rather, the

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important issue is that the present application has *not disclosed any* specific, substantial, or credible utility that is *directly* associated with the polypeptides of the present invention. There is no specific, substantial, or credible utility to be "accepted". The specification merely speculates, based on the sequence similarity, that disclosed zcytor14 would have similar utility as other known proteins in the family, such as IL-17R. As addressed in the last Office Action, generally, the art acknowledges that function cannot be predicted based solely on structural similarity to a known protein, and many examples have been seen that two members of a protein family share sequence homology, yet have distinct functional properties. Applicants have not provided fact or evidence to support the contrary assertion, and contrary to applicants assertion, the Examiner has cited art in the rejection to substantiate the assertions therein. Therefore, an established utility for IL-17 and IL-17R cannot be automatically applied to "Zcytor14" in the absence of supporting evidence. While it might be possible that the Zcytor14 protein is a member of IL-17R family, and upon further research, a specific, and substantial utility might be found for the claimed isolated nucleic acid and/or the polypeptide encoded thereby. This further characterization, however, is part of the act of invention, and until it has been undertaken, the claimed invention is incomplete.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-13 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial or credible utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons set forth in the last Office Action, paper No. 9, mailed on 26 November 2002, at page 4, and the reasons above, as the issue and the argument are based on the same basis.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "*an* amino acid sequence" in lines 3 and 4, which renders the claims indefinite because it indicates more than one amino acid sequence, while said nucleic acid molecule seems to encode only one amino acid sequence, unless fragments of SEQ ID NO:2 or 5 are intended. As such, the metes and bounds of the claim, therefore, cannot be determined.

The remaining claims are rejected for depending from an indefinite claim.

Conclusion:

No claim is allowed.

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Advisory Information:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

~~If attempts to reach the examiner by telephone are unsuccessful, the examiner's~~ supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



**LORRAINE SPECTOR
PRIMARY EXAMINER**

Dong Jiang, Ph.D.
Patent Examiner
AU1646
7/18/03